CLAIMS

What is claimed is:

1 1. A method for treating cancer comprising administering to a

2 subject having cancer a sufficient amount of a compound having the formula:

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4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a

5 pharmaceutically acceptable salt of the tautomer to provide a C_{max} of about 20

6 to 4000 ng/mL of the compound in the subject's plasma or a C_{max} of about 40

7 to 8000 ng/mL of the compound in the subject's blood.

1 2. The method of claim 1, wherein the amount of the compound is

2 sufficient to provide a C_{max} of about 50 to 500 ng/mL of the compound in the

3 subject's plasma or a C_{max} of about 100 to 1000 ng/mL of the compound in the

4 subject's blood.

- 1 3. The method of claim 1, wherein the amount of the compound is
- 2 sufficient to provide a C_{max} of about 50 to 250 ng/mL of the compound in the
- 3 subject's plasma or a C_{max} of about 100 to 500 ng/mL of the compound in the
- 4 subject's blood.
- 1 4. The method of claim 1, wherein the amount of the compound is
- 2 sufficient to provide a C_{max} of about 75 to 150 ng/mL of the compound in the
- 3 subject's plasma or a C_{max} of about 150 to 300 ng/mL of the compound in the
- 4 subject's blood.
- 1 5. The method of claim 1, wherein the amount of the compound is
- 2 sufficient to provide a C_{max} of about 100 to 2000 ng/mL of the compound in
- 3 the subject's plasma or a C_{max} of about 200 to 4000 ng/mL of the compound in
- 4 the subject's blood.

- 1 6. The method of claim 1, wherein the amount of the compound is
- 2 sufficient to provide a C_{max} of 100 to 1000 ng/mL of the compound in the
- 3 subject's plasma or a C_{max} of about 200 to 2000 ng/mL of the compound in the
- 4 subject's blood.
- 1 7. The method of claim 1, wherein the lactate salt of the compound
- 2 is administered to the subject and the subject is a human.
- 1 8. The method of claim 7, wherein the lactate salt is in an aqueous
- 2 solution and is administered orally to the human subject.
- 1 9. A method for treating cancer comprising administering to a
- 2 subject having cancer a sufficient amount of a compound having the formula:

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- 4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a
- 5 pharmaceutically acceptable salt of the tautomer to provide about 10 to 2,000
- 6 ng/mL of the compound in the subject's plasma 24 hours after administration
- 7 or about 20 to 4,000 ng/mL of the compound in the subject's blood 24 hours
- 8 after administration.
- 1 10. The method of claim 9, wherein the amount of the compound
- 2 administered is sufficient to provide about 20 to 1,000 ng/mL of the compound
- 3 in the subject's plasma 24 hours after administration or about 40 to 2,000
- 4 ng/mL of the compound in the subject's blood 24 hours after administration.
- 1 11. The method of claim 9, wherein the amount of the compound
- 2 administered is sufficient to provide about 40 to 500 ng/mL of the compound
- 3 in the subject's plasma 24 hours after administration or about 80 to 1,000
- 4 ng/mL of the compound in the subject's blood 24 hours after administration.

- 1 12. The method of claim 9, wherein the amount of the compound
- 2 administered is sufficient to provide about 40 to 250 ng/mL of the compound
- 3 in the subject's plasma 24 hours after administration or about 80 to 500 ng/mL

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- 4 of the compound in the subject's blood 24 hours after administration.
- 1 13. The method of claim 9, wherein the subject is a human.
- 1 14. The method of claim 13, wherein the lactate salt of the
- 2 compound is administered to the subject.
- 1 15. The method of claim 14, wherein the lactate salt is in a pill,
- 2 capsule, tablet, gelcap, caplet, suspension, or aqueous solution and is
- 3 administered orally to a human subject.
- 1 16. The method of claim 9, wherein the compound is administered
- 2 as a pharmaceutical composition comprising fructose.
- 1 17. The method of claim 16, wherein the pharmaceutical
- 2 composition further comprises a flavoring agent.
- 1 18. The method of claim 17, wherein the flavoring agent comprises
- 2 tetrarome mandarine flavor.
- 1 19. The method of claim 18, wherein the pharmaceutical
- 2 composition further comprises water.
- 1 20. The method of claim 9, further comprising mixing the solid
- 2 compound with water to form an aqueous mixture before administering the
- 3 compound to the subject.
- 1 21. The method of claim 9, wherein the compound is administered
- 2 as a pharmaceutical composition selected from granules, powders,
- 3 suspensions, tablets, pills, capsules, gelcaps, caplets, emulsions, syrups,
- 4 elixirs, slurries, sprays, aerosols, or solutions.

- 1 22. The method of claim 21, wherein the pharmaceutical
- 2 composition is selected from tablets, pills, capsules, gelcaps, or caplets.
- 1 23. The method of claim 9, wherein the compound is administered
- 2 by injection as a short bolus, slow infusion, or long-term infusion.
- 1 24. The method of claim 23, wherein the injection is administered
- 2 once, twice, three times, or four times daily.
- 1 25. The method of claim 9, wherein the amount of the compound
- 2 administered to the subject ranges from 0.25 to 30 mg/kg body weight of the
- 3 subject.
- 1 26. The method of claim 9, wherein the amount of the compound
- 2 administered to the subject ranges from about 25 to 1500 mg/day.
- 1 27. The method of claim 9, wherein the amount of the compound
- 2 administered to the subject ranges from about 200 to 500 mg/day.
- 1 28. The method of claim 9, wherein the cancer to be treated is a
- 2 solid tumor.
- 1 29. The method of claim 9, wherein the cancer to be treated is a
- 2 leukemia.
- 1 30. The method of claim 9, wherein the cancer to be treated is
- 2 selected from prostate, colorectal, breast, multiple myeloma, pancreatic, small
- 3 cell carcinoma, acute myelogenous leukemia, chronic myelogenous leukemia,
- 4 myelo-proliferative disease, nonsmall cell lung, small cell lung, chronic
- 5 lymphoid leukemia, sarcoma, melanoma, lymphoma, thyroid, neuroendocrine,
- 6 renal cell, gastric, gastrointestinal stromal, glioma, brain, or bladder.
- 1 31. The method of claim 9, further comprising administering the
- 2 compound as part of a treatment cycle, wherein the treatment cycle
- 3 comprises administering the amount of the compound daily for 7, 14, 21, or 28
- 4 days, followed by 7 or 14 days without administration of the compound.

- 1 32. The method of claim 31, wherein the treatment cycle comprises
- 2 administering the amount of the compound daily for 7 days, followed by 7
- 3 days without administration of the compound.
- 1 33. The method of claim 31, wherein the treatment cycle is repeated
- 2 one or more times.
- 1 34. The method of claim 31, further comprising administering the
- 2 amount of the compound once, twice, three times, or four times daily during
- 3 the administration phase of the treatment cycle.
- 1 35. The method of claim 9, further comprising administering the
- 2 amount of the compound once, twice, three times, or four times daily or every
- 3 other day during a course of treatment.
- 1 36. A method for treating cancer comprising administering to a
- 2 subject having cancer a sufficient amount of a compound having the formula:

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- 4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a
- 5 pharmaceutically acceptable salt of the tautomer to provide an AUC of about
- 6 500 to 60,000 ng*h/mL of the compound in the subject's plasma or about 750
- 7 to 120,000 ng*h/mL of the compound in the subject's blood.
- 1 37. The method of claim 36, wherein the AUC is about 1,000 to
- 2 30,000 ng*h/mL of the compound in the subject's plasma or about 1,500 to
- 3 60,000 ng*h/mL of the compound in the subject's blood.
- 1 38. The method of claim 36, wherein the AUC is about 2,000 to
- 2 15,000 ng*h/mL of the compound in the subject's plasma or about 3,000 to
- 3 30,000 ng*h/mL of the compound in the subject's blood.

1 39. A method for determining a metabolic profile for a compound

2 having the formula:

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4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a

5 pharmaceutically acceptable salt of the tautomer, in a subject, the method

6 comprising measuring the amount of at least one metabolite of the compound

7 in one or more samples of urine, blood, or tissue taken from the subject.

1 40. The method of claim 39, wherein the at least one metabolite is

2 an N-oxide compound having the formula:

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1 41. The method of claim 39, wherein the at least one metabolite is

2 an N-desmethyl compound having the formula:

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1 42. The method of claim 41, wherein the at least one metabolite

2 further includes a second metabolite that is an N-oxide compound having the

3 formula:

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- 1 43. The method of claim 41, wherein the metabolite is measured by
- 2 ultraviolet spectroscopy or liquid chromatography-mass spectroscopy.
- 1 44. A method of determining the amount of a compound having the
- 2 formula:

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- 4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a
- 5 pharmaceutically acceptable salt of the tautomer in a subject, the method
- 6 comprising measuring the amount of the compound in a sample of urine,
- 7 blood, or tissue taken from the subject after the compound has been
- 8 administered to the subject.
- 1 45. The method of claim 44, further comprising measuring the
- 2 amount of a metabolite of the compound in the sample.
- 1 46. The method of claim 45, wherein the metabolite is an N-oxide
- 2 compound having the formula:

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1 47. The method of claim 46, wherein the metabolite is an N-

2 desmethyl compound having the formula:

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1 48. The method of claim 44, further comprising withdrawing two or

2 more samples from the subject at different times after the compound has

3 been administered to the subject.

1 49. A method for treating cancer comprising administering to a

2 subject having cancer a compound having the formula:

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4 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a

5 pharmaceutically acceptable salt of the tautomer, wherein the amount of

6 compound administered to the subject in a first treatment cycle is 25 mg per

7 day, and the amount of compound administered is increased with each

8 subsequent treatment cycle until either 1500 mg of compound is administered

9 to the subject per day or dose-limiting toxicity is observed in the subject.

1 50. The method of claim 49 wherein the amount of compound

2 administered is doubled with each subsequent treatment cycle after the first.

1 51. The method of claim 50 wherein the treatment cycle comprises

2 administering the same amount of the compound daily for 7 days followed by

3 7 days without administration of the compound.

- 1 52. A method of treating cancer, comprising administering to a
- 2 subject having cancer, a sufficient amount of a compound having the formula I

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- 5 a pharmaceutically acceptable salt thereof, a tautomer thereof, or a
- 6 pharmaceutically acceptable salt of the tautomer, and exposing the subject to
- 7 one or both compounds of formula II and formula III selected from:

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II or

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III,

- 12 whereby one or both of the compounds of formula II and formula III are
- produced by metabolism of the compound of formula I by the subject, to 13
- provide a combined C_{max} for one or more of the compounds of formula I, 14
- 15 formula II, and formula III ranging from about 20 to about 4000 ng/mL in the
- subject's plasma or a combined C_{max} for one or more of the compounds of 16
- formula I, formula II, and formula III ranging from about 40 to about 8000 17
- 18 ng/mL in the subject's blood.

- 1 53. A method for treating cancer comprising exposing a subject
- 2 having cancer to an amount of one or more compounds having a formula
- 3 selected from:

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F NH₂ N NH N O

7 an active metabolite thereof, a pharmaceutically acceptable salt thereof, a

8 tautomer thereof, or a pharmaceutically acceptable salt of the tautomer,

9 sufficient to provide a combined C_{max} of about 20 to 4000 ng/mL of the one or

10 more compounds in the subject's plasma or a combined C_{max} of about 40 to

11 8000 ng/mL of the one or more compound in the subject's blood.

1 54. The method of claim 53, wherein the amount of the one or more

2 compounds provides a C_{max} for one of the compounds of about 35 to 2600

3 $\,$ ng/mL in the subject's plasma or a $\,$ C_{max} for one of the compounds of about 35

4 to 6000 ng/mL in the subject's blood.

1 55. The method of claim 53, wherein the amount of the one or more

2 compounds provides a C_{max} for one of the compounds of about 35 to 1200

3 ng/mL in the subject's plasma or a C_{max} for one of the compounds of about 50

4 to 2400 ng/mL in the subject's blood.

1 56. The method of claim 53, wherein the compound of formula:

3 the pharmaceutically acceptable salt thereof, the tautomer thereof, or the

4 pharmaceutically acceptable salt of the tautomer is administered to the

5 subject.

6 57. The method of claim 53, wherein the compound of formula:

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8 the pharmaceutically acceptable salt thereof, the tautomer thereof, or the

pharmaceutically acceptable salt of the tautomer is administered to the

10 subject.

1 58. The method of claim 53, wherein the compound of formula:

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3 the pharmaceutically acceptable salt thereof, the tautomer thereof, or the

4 pharmaceutically acceptable salt of the tautomer is administered to the

5 subject.